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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/614,448

07/07/2003

Lawrence A. Shimp

285-180 PCT CIIP

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25763 7590 07/27/2007

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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

07/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/614,448

Applicant(s)

SHIMP, LAWRENCE A.

Examiner

KAILASH C. SRIVASTAVA

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-64 and 66-88 is/are pending in the application.
- 4a) Of the above claim(s) 2-29, 36-51, 53-63 and 66-88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 30-35, 52 and 64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Your response, amendments and remarks filed 03 May 2007 in response to Notice of Non-Compliant amendment mailed 03 April 2007 are acknowledged and entered.
2. Response, and remarks filed 11 December 2006 in response to Office Action mailed 11 August 2006 are also acknowledged and entered.

General Matters

3. Contrary to applicant's assertion in the header for each page of response and amendments, and in the body of response at Page 12, Line 4 of Response filed 11 December 2006, the Office Action to which the response is filed on 11 December 2006 was neither mailed on 11 September 2006 (See Headers, Line 2), nor on 11 August 200005 (See, Line 4, Page 12 of the response filed 11 December 2006), said Office Action was mailed 11 August 2006 (See Page 1, Line 14 of Office Action mailed 11 August 2006). Please correct the record accordingly. If, however, applicant has proof to the contrary, applicant should clarify the record.
4. The present Office Action jointly addresses the responses, amendments and remarks filed on 03 May 2007 and on 11 December 2006 respectively.
5. Note, the Amendment filed 03 May 2007 clearly states, "This listing of Claims will replace all prior versions, and listings, of claims in the application" (See Page 3, Lines 4-5). Accordingly, any and all rejections in the instant Office action are drawn to the set of non-withdrawn and non-canceled Claims accompanying the amendment and response filed 03 May 2007.
6. Incorporation of application identifiers (e.g., U.S. Non-provisional Application Number, Filing Date for said application, Attorney Docket Number, Inventor's name, Art Unit USPTO, and Examiner's name) in the header of the each page of the amendment and responses filed 09 May 2007 and 30 November 2006 is greatly appreciated.

Claims Status

7. Claims 1-88 are pending.
8. Claim 65 has been cancelled.

9. Claims 2-29, 31, 36-51, 53-63 and 6-88 remain withdrawn.
10. Claims 1, 30, 32-35, 52 and 64 have currently been amended.
11. Claims 1, 30, 32-35, 52 and 64 are under examination.
12. Claims 1, 30, 32-35, 52 and 64 are examined on merits.
merits.

Claim Objections in Office Action mailed 11 August 2006

13. In responding to rejections under 35 U.S.C. §112, 2nd Paragraph in Office Action mailed 11 August 2006, applicant repeatedly refers "Examiner objected to" (see Page 15, Lines 18, 22 and 27 and Page 6, Line 5). Applicant to note that. Claim 1 was not objected to, rather, Claims 30, 32-35, 52 and 64-65 were objected in the Office Action mailed 11 August 2006 (e.g., See page 4, Line 19).
14. Applicant has discussed objection of Claim 8 in response filed 11 December 2006 (See response Page 16, Line 3-4). Claim 8 has been withdrawn from consideration (See Office Action mailed 11 August 2006, Page 4, item 8, Line 1). Appropriate correction to the record is required.

Claim Rejections Under 35 U.S.C. § 112, 2nd Paragraph

15. Despite applicant referring to rejections under 35 U.S.C. §112, 2nd Paragraph in Office Action mailed 11 August 2006 as "Examiner objected", to expedite the prosecution of elected claims in the instant application, applicant's response is taken as response to rejections under 35 U.S.C. §112, 2nd Paragraph in Office Action mailed 11 August 2006. Accordingly, based on said remarks and amendments, rejections of Claims 1, 30, 32-35, 52 and 64-65 under 35 U.S.C. §112, 2nd Paragraph in Office Action mailed 11 August 2006 is withdrawn.

Claim Rejections Under 35 U.S.C. § 103(a)

16. The following is a quotation of 35 U.S.C. §103(a) that forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claims 1, 30, 32-35, 52 and 64 are rejected under 35 U.S.C. § 103 (a) as obvious over the combined teachings from Sierra et al. (WO 98/31403) in view of Peterson (U.S. Patent 5, 730,933) and further in view of Higgins (U.S. Patent 5,753, 182).

In response to rejections to Claims 1, 30, 32-35, 52 and 64 under 35 U.S.C. § 103 (a) cited *supra* in Office Action mailed 30 November 2006, applicant, citing case laws argues that combination of these references “is improper” (See Remarks filed 11 December 2006, Page 14, Line 15) and further argues that these references, alone or in combination do not establish a *prima facie* case of obviousness to make the applicant’s invention claimed in Claims 1, 30, 32-35, 52 and 64 unpatentable obvious. Applicant further argues polymers are not biological materials and further that while polymers may be used in the body, they do not interact with tissues, but rather, simply become encapsulated by fibrous tissue before being walled off” (Remarks, Page 14, Lines 6-8).

Applicant’s claimed invention according to the amended claims filed 03 May 2007 is drawn to a method “effective to protect one or more property of a biological material during the sterilization process comprising packaging a biological material, providing a protective atmosphere within the packaged material by at least partially removing the original atmosphere under vacuum and replacing said space with a reducing atmosphere, or a mixture of a reducing atmosphere and an inert atmosphere”. In dependent claims for said method, the biological material is bone and inert atmosphere is nitrogen gas, and reducing atmosphere is hydrogen

Regarding Claims 1, 30, 32-35, 52 and 64, at Page 5, item 15, Lines 18-35 of the Office action mailed 11 August 2006, Sierra et al. clearly teach a method to sterilize a collagen based adhesive by first lyophilizing or freeze drying under vacuum and subsequently sterilizing with a gamma irradiation, while keeping the biological material cool. Collagen is a polymeric biological material constituted of amino acids) note that amino acids are monomers). Peterson teaches a method of radiation sterilization of a biological material, wherein prior to sterilization said material is subjected to vacuum or inert gaseous atmosphere of argon, helium, nitrogen (nitrogen is reducing atmosphere and argon is inert) and said material is held in a sealed or unsealed packet during sterilization and Higgins teaches sterilization of a prepackaged biological material, wherein said biological material is packaged in an atmosphere of hydrogen). Thus, each of the components claimed in the method of instantly claimed invention are clearly taught in the prior art references. Furthermore, since each of the references teach:

- a. Radiation sterilization or sterilization of a biological material;
- b. Treating the biological material to vacuum;

c. Presence of a reducing gaseous (i.e., hydrogen or nitrogen) atmosphere around the packaged biological material;

d. Presence of an inert atmosphere (e.g., argon, or helium) around the biological material;

the suggestion to combine the references is within the references because of the common element of sterilizing a biological material that is packaged and is vacuum treated prior to radiation sterilization. The torque to which the material is subjected is within the purview of routine optimization of a method for an artisan. Furthermore, since each of the elements claimed in the instant invention are taught by the references as combined there is an expectation of success of the prior art process/method.

Furthermore, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art at the time the invention was made. See *In re Keller* 642. F. 2d 413, 208 USPQ 871 (CCPA 1981). Note that although each of the Examiner-cited references by themselves may not teach every component in the same order or manner as claimed in the elected claims under prosecution in the instant application, these references are not relied upon exclusively but in combination.

Moreover, the 35 U.S.C. §103 statute does not require that the prior art identically disclose or Describe applicant's invention but rather that no patent should be obtained if the subject matter as a whole would have been obvious to persons having ordinary skill in this art at the time the claimed invention was made. Furthermore, the instantly claimed invention would have also been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for the same purpose and also because of the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of each of the ingredients, *In re Sussman*, 1943 C.D. 518.

Applicant's arguments cited *supra* have been fully and carefully considered, but are not persuasive for the reasons of record at Page 5, item 12, Line 9 to Page 6, Line 23 of the Office action mailed 31 July 2006 and further for the reasons explained in the preceding paragraph.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of

the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, those reasons are cited at Page 5, item 15, Lines 18-35 of the Office action mailed 11 August 2006 and for additional reasons as discussed *supra*. Furthermore, a rejection under 35 U.S.C. § 103 (a) based upon the combination of references is not deficient solely because the references are combined based upon a reason or technical consideration which is different from that which resulted in the claimed invention (*Ex parte Raychem Corp*, 17 U.S.P.Q. 2d 1417).

In response to applicants' arguments against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

CONCLUSION

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

19. For the aforementioned reasons, no claims are allowed.


20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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23 July 2007


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